



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,123	12/29/1998	ROBERT A. RAY	6328-21	3601

7590 09/21/2004

J. RODMAN STEELE, JR., ESQ.  
AKERMAN, SENTERFITT & EIDSON, P.A.  
222 LAKEVIEW AVENUE SUITE 400  
POST OFFICE BOX 3188  
WEST PALM BEACH, FL 33402-3188

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/222,123	Applicant(s) RAY ET AL	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-21, 24-27, 29-32 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-21, 24-27, 29-32 and 34-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' arguments filed on May 24, 2004.

Claims 19-21, 24-27, 29-32 and 34-42 are pending.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 19-21, 24-27, 29-32 and 34-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over European publication 0022377 to Levine in view of US Patent 4,521,520 to Jacke.

Levine discloses a device for obtaining a biological sample to be analyzed. The device comprises a handle end (4) and a collection end (8). On the collection end of the device, the reference teaches that there is an opening (6). Also, there is an absorbent pad (10) on the collection end of the device. See figure 1. Levine discloses that the handle end of the device may be made from a polymeric material, such as polyethylene. The device may be folded to form a pouch in which the sample is stored. When folded, there exists an opening (18) which is disposed over the collection pad containing the sample. This opening may serve as a means for facilitating removal of a portion of the collection pad.

Levine differs from the instantly claimed invention in that it fails to teach polyvinyl alcohol as the absorbent material for the pad.

Jacke teaches devices and method for obtaining biological samples. The device of Jacke comprises a handle end having an absorbent pad attached to the collection end. The absorbent pad is polyvinyl alcohol (col. 3, lines 41-47). The polyvinyl alcohol collection pad contains

Art Unit: 1743

several pores (70). With respect to the recited pore size, the ordinarily-skilled artisan would have been able to determine a suitable pore size according to the sample being collected and the analysis being performed. Jacke teaches that the pad may have reagents incorporated therein to assist in analyzing the sample. Jacke further teaches incorporate a receptacle with in kits where the collection will be performed at home.

It would have been obvious to one of ordinary skill in the art to use a polyvinyl alcohol pad in the device of Levine because of its ability to catch and hold a biological sample. Using a polyvinyl alcohol absorbent material reduces the changes of losing sample and increases the chances of obtaining a sample sufficiently large enough to perform analysis.

With respect to the presence of instructions in the kit, it would have been obvious to one of ordinary skill in the art to include instructions in the kit of Levine, especially where the kit is to be used at home, to make sure that the user operates the devices in the correct manner and collects the sample in the correct manner.

With respect to the claims reciting urine as the particular sample to be collected, the claims are not limited by such recitation because the patentability of claims directed to a device lies in structural components of the device and not materials the device is intended to work on.

### ***Response to Arguments***

3. Applicant's arguments filed May 24, 2004 have been fully considered but they are not persuasive. In response to the obviousness rejection over Levine in view of Jacke, Applicants argue that Levine fails to teach a means for facilitating removal of a portion of the collection pad. As explained at page 5 of Levine, the test sample is collected onto the collection pad (10), which is affixed to a strip (14). After collection, one side of the strip is folded onto the side

Art Unit: 1743

having the collected sample. The aperture (18) is then located directly on top of the collected sample.

It should be noted that Applicants' specification defines the "means for facilitating removal of a portion of the collection pad" as an aperture through the strip onto which the collection pad is affixed (specification pages 5-6 and 12). Levine provides an aperture in a strip that has a collection pad affixed thereto. While Levine may not disclose that the aperture functions in "facilitating removal of a portion of the collection pad", the means by which this function takes place (i.e. the aperture) is disclosed. MPEP 2182 provides that if the specification defines what is meant by the means plus function limitation for the purpose of the claimed invention, the examiner should interpret the limitation as having that meaning. Thus, the Levine reference meet Applicants' claimed means plus function limitation.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1743


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lic

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700